

## **REMARKS**

The above Amendments and these Remarks are in reply to the Office Action mailed March 3, 2006.

Claims 25-44 were pending in the Application prior to the outstanding Office Action. In the Office Action, the Examiner rejected claims 25-44. Claims 26-28 are amended and Claim 44 is cancelled. Claims 25-43 remain for the Examiner's consideration. Reconsideration and withdrawal of the rejections are respectfully requested. The Applicant respectfully requests the opportunity to interview the Examiner by telephone at the Examiner's earliest convenience to discuss the claimed ranges and the nature of the Applicant's double salt invention.

## **AMENDMENTS TO THE SPECIFICATION**

The Applicant has amended the specification by importing the claims of the originally filed application, 09/463024 (hereinafter '024), into the patent application (see paragraphs [0047]-[0066]). "Matter not in the original specification, claims or drawings is usually new matter". MPEP § 608.04(a). Here, the matter is in the original claims of the '024 application and therefore not new matter. Further, "[u]nder 35 U.S.C. 120, a claim in a U.S. application is entitled to the benefit of the filing date of an earlier U.S. filed application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the earlier filed application". MPEP § 201.11(I).

### **Claim Objections**

A) Claims 26 and 27 are objected to because they were improperly dependent on Claim 1, which was previously cancelled. Claims 26 and 27 have been amended to be dependent on claim 25. Accordingly, it is requested that the objections to claims 26 and 27 be withdrawn.

### **Claim Rejections - 35 U.S.C. § 112**

**B)** Claims 26-30, 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description. Claim 25 recites the limitation “14-26% by weight of calcium; 24-40% by weight of potassium, and “14-24% by weight of sodium”, “each calculated as a percentage of the total hydroxycitric acid content of said composition”. The Examiner states that Claims 26-27 have calcium, potassium and sodium ranges outside of the instant claim 25. The Examiner has not considered two factors. Firstly, Claim 26 limits the composition to approximately 40% by weight of hydroxycitric acid. Secondly, Claim 26 states the calcium, potassium and sodium compositions as “calculated as a percentage of the total weight of said composition”. The effect of these two changes is important for the range of the claims when stated as a percentage of the total weight of said composition.

Since Claims 26 and 27 both recite that the composition ‘comprises’, then one way of fulfilling the limitations of the proposed composition ratios of these claims is by introducing excipients that do not contain Ca, K or HCA. Further, a composition based on a pure HCA double salt compound may contain approximately 16% Ca and 26% K each calculated as a percentage of the total hydroxycitric acid content of said composition. Such a compound meets the explicit limitations of Claim 25. If the above compound was mixed with excipients and thereby diluted with the excipient, and the excipients constituted 30 % of the food product calculated as a percentage of the total weight of said composition then the product will be at least approximately 40 % by weight of HCA calculated as a percentage of the total weight of said composition, thus fulfilling limitation (a) of Claim 26. Further, the salt compositions will have fallen to approximately 11% Ca and 18% K calculated as a percentage of the total weight of said composition, thus fulfilling limitations (b) and (c) of Claim 26. Thus this embodiment of a food product with the proposed ratio of excipients meets the limitations of Claim 26.

Because claims 25-27 preserve the original language of claims 1, 12 and 13, the Applicant believes that there is antecedent basis and that amended claims 26 and 27 are properly dependent on claim 25.

### Claims 28, 40 and 41

Applicant has amended independent Claim 28 removing the limitation “wherein the composition is bound together to form a single molecule” from the claim. The remaining language of Claim 28 is supported in the specification at least at page 3, 3<sup>rd</sup> full paragraph.

Examiner states that claims 40 and 41 are not supported by the specification. In particular Examiner appears to believe that a claim to a beverage as opposed to a food product is not supported. The Examiner cites to page 10, line 28 – page 11, lines 2 of the application. This section of the application reads “[w]hen provided for oral administration as a processed food product, such as a *beverage* or a snack bar, the hydroxycitric acid content will desirably comprise approximately 0.001 to 25%, preferably 0.05 to 5% by weight of the total weight of the food product” (emphasis added). The Applicant has thereby defined “a processed food product” to include “a beverage” or “a snack bar”. As such the Applicant believes that the claim as previously presented is supported by the original specification.

The Applicant sets forth the places in the ‘024 application and the amended specification in which Claims 26, 27, 29, 30, 42 and 43 are explicitly supported.

### Claim 29

According to the Examiner the limitation “less than approximately 4% by weight” of the lactone form of hydroxycitric acid” is not set forth in either the instant specification or the ‘024 parent.

On page 15, Claim 17 of the ‘024 application states the limitation “... wherein the lactone forms of hydroxycitric acid comprise less than approximately 4% by weight of the total

hydroxycitric acid content of the composition”, which is now part of the specification. Thus, Claim 29 is supported in the amended specification at least at paragraph [0070].

#### Claim 30

According to the Examiner the limitation ““less than approximately 2% by weight” of sodium” is not set forth in either the instant specification or the ‘024 parent.

On pages 13-15, Claims 2 and 16 of the ‘024 application state the limitation “... sodium comprises less than approximately 2% by weight”, which is now part of the specification. Thus, Claim 30 is supported in the amended specification at least at paragraphs [0055] and [0069].

#### Claim 26 and 42

According to the Examiner the limitation “comprising, in part, 5 to 12% by weight of sodium” is not set forth in either the instant specification or that of the ‘024 application.

On page 14, Claim 6 of the ‘024 application states the limitation “... or approximately 5 to 12% by weight of sodium”, which is now part of the specification. Thus, Claims 26 and 42 are supported in the amended specification at least at paragraphs [0059]-[0064].

#### Claim 27 and 43

According to the Examiner the limitation “comprising, in part, 9 to 13% by weight of calcium” is not set forth in either the instant specification or that of the ‘024 application.

On page 14, Claim 8 of the ‘024 application states the limitation “... calcium comprises approximately 9 to 13% by weight”, which is now part of the specification. Thus Claims 27 and 43 are supported in the amended specification at least at paragraph [0061].

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the 112 rejection.

### **Claim Rejections - 35 U.S.C. § 103**

C) Claims 28, 31, 38-39 and 44 are rejected under 35 U.S.C. 103(a), as being unpatentable over US 5,612,039 (hereafter '039) in view of Clouatre et al. ("The Diet and Health Benefits of HCA") (hereafter "*Clouatre*").

The '039 patent teaches a calcium salt of hydroxycitric acid. The Examiner argues that the calcium hydroxycitric acid composition advanced by '039 has negligible odor, is clear in solution and has minimal hygroscopicity. (Page 6, lines 7-9). A word search of the '039 patent reveals no occurrences of the word 'minimal' or 'hygroscopic'; one occurrence of the word 'odor' where the odor of the composition is described as "characteristic smoky-herbal" ('039, column 6 line 8-9) and one occurrence of the word 'clear' in the context of "clarity" where the clarity is described as "clear with residue" ('039, column 6 line 12). The description of a residue is important. When a water insoluble compound is mixed in water the water remains clear and a residue is formed on the bottom of the vessel comprising the compound added. Thus based on '039 description calcium hydroxycitric acid is partially insoluble. This is to be expected given the teaching of the Applicant "[c]alcium hydroxycitric acid is only moderately soluble in water" ('024, page 3, last sentence). Further, the characteristics actually described by '039 include a light tan color and a characteristic salty herbal taste ('039, column 6 line 6-9). As such the calcium hydroxycitric acid is not clear, does not have negligible odor, does not have negligible taste, does not have negligible color and is at least partially insoluble.

The Examiner's previous response does not fully explain the grounds of the rejection or the premise upon which the rejection is based. "In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application". MPEP 707.07(f). Therefore, the Examiner is requested to indicate the basis upon which he forms this position.

The Examiner argues that *Clouatre* teaches “the addition of potassium to a composition can augment the weight loss effects of hydroxycitric acid”. In fact, *Clouatre* teaches stabilizing hydroxycitric acid in its non lactonized form by combining it with calcium, potassium OR sodium (*Clouatre*, page 39 1st full paragraph, 1<sup>st</sup> sentence). Thus *Clouatre* is referring to exchanging the free acid form of hydroxycitric acid with a single salt (either calcium, potassium or sodium) form of hydroxycitric acid. The Applicant notes that exchanging the calcium salt of hydroxycitric acid for the potassium salt of hydroxycitric acid is not the Applicants invention. An embodiment of Claim 28 of the applicant’s invention is a double salt of hydroxycitric acid comprising hydroxy citric acid, calcium and potassium (e.g., calcium/potassium hydroxycitric acid double salt).

This invention is both novel and non-obvious over potassium hydroxycitric acid as taught by *Clouatre* and calcium hydroxycitric acid as taught by ‘039. The invention does not have the odor, color and hygroscopic problems associated with potassium hydroxycitric acid. In contrast, the inventor unexpectedly found, that the calcium/potassium hydroxycitric acid double salt is highly soluble in water, being up to 25% weight to volume soluble in water (‘024, page 4, first sentence). As such the double salt produced extremely surprising results.

On page 6 of the March 3, 2006 office action, first full paragraph, the Examiner suggests the addition of potassium to the calcium salt of hydroxycitric acid is what is not taught. This statement misstates what is non-obvious about the Applicants invention. The Applicant reiterates that adding potassium to the calcium salt of hydroxycitric acid is not the Applicant’s invention. By performing the Examiner’s experiment, just ‘adding’ potassium (presumably the Examiner means a soluble salt form of potassium and not potassium metal) to calcium hydroxycitric acid, the clarity, odor, taste, color and solubility problems of calcium hydroxycitric acid would not have been overcome.

As such neither ‘039 nor *Clouatre* teach or suggest the present invention. As such, Claim 28 was not obvious at the time the invention was made. The Examiner is respectfully requested to reconsider this ground of rejection. Claims 31-39 all directly or indirectly depend from independent claim 28, and are therefore believed patentable for at least the same reasons as the independent claim 28 and because of the additional limitations of these claims.

**D)** Claims 25, and 28-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,536,516 in view of WO 98/28989.

The Applicant notes that the '989 application was filed on June 29, 1998 and is a continuation in part of application No PCT/FI97/00797 which was filed December 17, 1997 and claims priority to a Finnish application 965251 filed December 30, 1996. As such the '989 application has an international filing date of December 17, 1997. The MPEP in section 1893.03(b) states that the international filing date is also the national stage filing date. As such, the '989 application does not have an earlier filing date than the priority date of the present application and is not available to be combined with the '516 patent.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the 103 rejections.

### CONCLUSION

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

A check in the amount of \$180.00 is enclosed to cover the required fee. The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Date: \_\_\_\_\_

5/4/06

Respectfully submitted,

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